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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/245,277 | 02/05/1999 | PAUL P. WORLEY | JHU1530-3 | 4724 |

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09/30/2005

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/245,277

Applicant(s)

WORLEY ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-68 and 72-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-68 and 72-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Formal matters

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Response to Amendment

2. Claims 65-68 and 72 have been amended, claims 64, 70 and 71 have been canceled and claims 73-75 have been added as requested in the amendment filed on August 17, 2005.

Following the amendment, claims 65-68 and 72-75 are pending in the instant application.

Claims 65-68 and 72-75 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on August 17, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

6. Claims 65-68 and 72-75 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in appropriate sections of previous office actions of record.

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To traverse the rejection, Applicant submits a declaration by Dr. Worley, which presents evidence that the protein of clone L-100 is associated with apoptosis. Applicant further argues that “the protein sequence of clone L-100 was later shown to be identical to axin 1 upregulated 1 [...]. Axin is a multidomain scaffold protein that has many functions in biological signaling pathways” (middle at page 6 of the Response). Applicant’s arguments and Declaration of Dr. Worley have been fully considered but are not persuasive for the following reasons.

The Declaration of Worley under 37 CFR 1.132 filed on August 17, 2005 is insufficient to overcome the rejection of claims 65-68 and 72-75 based upon 35 U.S.C. 101 as set forth in the last Office action because: the Declaration provides evidence that the protein sequence of L-100, or SEQ ID NO: 27, is associated with apoptosis; however, the asserted specific and substantial practical utility for the claimed molecules is to be used as markers of seizure events in neuronal tissue. As fully explained in the previous office actions of record, the record does not support Applicant’s position that the characterization of a nucleic acid, which is upregulated during experimental seizure, is useful as a marker for seizures in neuronal tissues. There appears to be no evidence presented in the instant specification, as filed, that the claimed polynucleotides are present/absent during seizure in neuronal tissue or are present at the specific altered levels that are directly associated with seizures. Therefore, based on the information presented by Applicant, the claimed molecules cannot be considered as biological markers for seizures. Furthermore, it is not clear and not explained in the Declaration, how the evidence presented therein regarding association of L-100 with apoptosis supports the asserted utility of the claimed invention as biomarker for seizures.

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With respect to structural identity of the instant L-100 protein with Axud 1 protein, it is not persuasive that the relationship between L-100 and Axud 1 protein supports the utility of the claimed nucleic acids. While the similarity of a polypeptide to another polypeptide with a known and established function, which supports its practical utility, would be sufficient to satisfy the requirement under 35 U.S.C. 101, in the instant case the identification of the novel protein L-100 as being identical to a protein that “has many functions in biological signaling pathways” only serves as a ground for further research to establish its patentable specific and substantial credible utility.

Thus, for reasons of record in the previous office actions and reasons explained above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

7. Claims 65-68 and 72-75 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.
8. Claims 66-68 and 73-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 66-68 and 70-71 in section 9 of Paper mailed on February 14, 2005.

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Applicant traverses the rejection on the premises that “as the invention provides both structural and functional characteristics [...], one of skill in the art would have been able to practice the invention, as claimed, at the time of filing of the invention without undue experimentation” (bottom at page 7 continuing to page 8 of the Response). Applicant further refers to the case law *In re Wright*, *Wang Labs Inc. v. Toshiba Corp.* and *Fujikawa v. Wattanasin* (page 7) to support the arguments that the instant invention is adequately described. Applicant’s arguments have been fully considered but are not persuasive for the reasons that follow.

First, it appears that Applicant is arguing concurrently enablement and written description rejections. Applicant is reminded that the instant rejection is based on lack of written description of the claimed molecular embodiments and, further, the written description provision of 35 U.S.C. §112 is severable from its enablement provision (*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d, 1115). Second, as fully explained in the previous office actions of record, to provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. In the instant case, the instant specification provides no written description of structure of the polynucleotide fragments, which are at least 12 or 40 bases in length, such nucleic acids expressed in response to seizures in a subject. There is no disclosure of complete or partial structure of the claimed nucleic acids, physical and/or chemical properties or structure/function correlation presented at the time of filing. Therefore, a skilled artisan clearly cannot envision the detailed chemical structure of the encompassed genus of nucleic acids, and as such, the instant specification fails to meet the written description requirement in accordance with 35 U.S.C. §112, first paragraph.

New grounds of rejection necessitated by amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 66-68 and 73-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 66 and 73 are directed to isolated nucleic acid molecules which hybridize to the nucleic acid molecule of SEQ ID NO: 26, which makes the claimed nucleic acid a complementary strand, and which further is expressed in response to seizure in a subject. Claims 67-68 and 74-75 are dependent claims. The prior art clearly does not teach how to produce a complementary nucleic acid, which encodes a polypeptide. The instant specification fails to provide any guidance or any working examples on how to practice the claimed invention. It would require substantial amount of undue experimentation on part of a skilled artisan in order to discover how to practice Applicant's invention as currently claimed.

Conclusion

10. No claim is allowed.

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

September 28, 2005